DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

April 2, 2015

Synaptive Medical Inc.
Mr. Cameron Piron
President
Mars Center, South Tower, 101 College Street, Suite 200
Toronto, ON M5G 1L7 Canada

Re: K142024
Trade/Device Name: BrightMatter Navigation System v1.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: March 24, 2015
Received: March 30, 2015

Dear Mr. Piron,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K142024

Device Name
BrightMatter Navigation System v1.0

Indications for Use *(Describe)*
BrightMatter Navigation System is intended as a planning and intraoperative guidance system to enable open and percutaneous computer assisted surgery. The system is indicated for medical conditions requiring neurosurgical cranial procedures where the use of computer assisted planning and surgery may be appropriate. The system can be used for intra-operative guidance where a reference to a rigid anatomical structure can be identified.

The system should be operated only by trained personnel such as surgeons and other clinic staff.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary**

I. SUBMITTER

Synaptive Medical Inc.
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Contact Person:
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Date Prepared: March 27, 2015

II. DEVICE

Name of Device: BrightMatter Navigation System v1.0
Common or Usual Name: Stereotaxic instrument
Classification Name: Stereotaxic instrument (21 CFR 882.4560)
Regulatory Class: II
Product Code: HAW

III. PREDICATE DEVICE

Stryker Navigation System – Cranial Module by Stryker Corporation, K062640
Date cleared: December 14, 2006

IV. DEVICE DESCRIPTION

The subject device, BrightMatter Navigation system, is a planning and image guided surgical system that enables computer assisted surgery where use of stereotactic image guidance may be considered appropriate. In particular, the device is suitable for neurosurgical cranial procedures. The planning functionality of the device is provided by an already cleared device, BrightMatter Planning (K140337). The remaining system provides a sequence of discrete workflow activities (or phases) that guide a surgeon through the process of data preparation for the surgical procedure. Then the device aids the surgeon in visualizing the location of the surgical tools relative to clinical images and physical location of the patient.
Following is a summary of steps involved in data preparation and registration of the patient's head position relative to pre-surgical clinical images:

- Importing plan and imaging data
- Reviewing and selecting a previously generated surgical plan
- Optionally fusing (merging or co-registering) additional imaging data
- Preparing and executing point-based registration

Following steps are provided as visualization tools during the execution of the surgical procedure:

- Aid in visualizing location of the surgical site as planned by the surgeon (using BrightMatter Planning software, K140337)
- For trajectory-centric procedures, help visualize insertion of tracked surgical tools by identifying location of surgical tool's position and orientation relative to clinical images and the surgical plan developed by the surgeon
- Visualize location of tracked surgical tools after the intended target location has been reached

Key functional components of the subject device are an optical tracking sub-system, navigated surgical tools, custom software application and an external display. The navigated surgical tools are tracked using single-use passive reflective markers (K033621) that are attached to the surgical tools prior to each surgical procedure.
The surgical display and tracking camera are mounted on an Auxiliary Cart. The computer is housed in a Navigation Cart.
As with many systems in the OR, not all components need to be sterile during use. The only sub-components that come in contact with the patient are the Pointing Tool, Port Reference Tool and Calibration Block. These tools fit in the limited contact duration category.

## V. INDICATION FOR USE

*BrightMatter Navigation System* is intended as a planning and intraoperative guidance system to enable open and percutaneous computer assisted surgery. The system is indicated for medical conditions requiring neurosurgical cranial procedures where the use of computer assisted planning and surgery may be appropriate. The system can be used for intra-operative guidance where a reference to a rigid anatomical structure can be identified.
The system should be operated only by trained personnel such as surgeons and other clinic staff.

The Indications for Use statement for BrightMatter Navigation System is identical to the predicate device with the exception that the subject device's statement does not enumerate specific supported clinical procedures. This difference does not affect the intended use of the subject device as a guidance system when the device is used as labeled. The safety and effectiveness of the subject device were established through verification and validation summarized below.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

*Design comparison summary:* Both the subject device and the predicate device, Stryker Navigation System – Cranial Module, help develop a treatment plan. This treatment plan is then used as input to image guided surgery. Both systems track the surgical tools using an optical 3D tracking system and the position and orientation of these tools are displayed relative to the clinical images of the patient. This information is used by the surgeon to guide the surgical instrument(s) to a target location designated by the surgeon. Both systems utilize a software sub-system that is workflow based. Hence, the overall design of the two systems are comparable. The only difference is that the subject device provides the additional capability of visualizing tractography information.

*Biocompatibility summary:* The subject device is comparable to the predicate device since the predicate device claims biocompatibility in its documentation and patient contacting parts of the subject device were tested per ISO 10993 and FDA Memo G95-1.

Following is a summary of biocompatibility tests conducted for patient contacting parts:

| Pointer Tool, Pointer Tool Tip and Port Reference Tool | | |
|---|---|---|
| **Test** | **Results** | **Conclusions** |
| Cytotoxicity: MEM Elution GLP | 0 score for based on degree of cellular destruction | Non-cytotoxic |
| Sensitization: ISO Guinea Pig Maximization Sensitization Test (GLP-2 Extracts) | None of the animals showed sensitization response greater than zero. | Devices do not elicit sensitization response |
| Irritation/Intracutaneous Toxicity: ISO Intracutaneous Irritation Test (GLP-2Extracts) | No significant dermal reactions at injected and control sites at 24, 48 and 72 hrs. | Do not cause tissue irritation |
| Acute Systemic Toxicity: ISO Materials Mediated Rabbit Pyrogen (GLP) | None of the animals had a temperature rise greater than or equal to 0.5 degrees. | Devices are non-pyrogenic. |
| Acute Systemic Toxicity: Acute Systemic Injection Test | None of the tested animals showed clinical signs of toxicity | Device contact is non-toxic |
| Rabbit pyrogen test | Detected endotoxin level is less than 0.005 EU/mL | Device is non-pyrogenic |

*Sterility summary*: The subject device is comparable to the predicate device since the predicate device's navigation tools are sterilizable and the subject device's end-user sterilizable components have been tested per AAMI TIR30 and TIR12 and validation demonstrated an SAL of $\leq 10^{-6}$.

*Technology comparison*: The predicate device utilizes active light sources on the surgical tool that are tracked using a stereoscopic camera while the subject device utilizes passive reflective markers on the surgical tools and the markers are illuminated by light sources located on the stereoscopic camera system. The accuracy of the subject device was characterized using a measurement phantom, Pointer Tool, Port Reference Tool and using point registration. Mean positional error was measured to be less than 2 mm and mean angular error was measured to be less than 2 degrees for both the tools. This performance was observed at the center and at the boundaries of the field of view of the tracking camera.

The predicate device supports video input from external microscope as an optional feature; however, the subject device does not provide this feature. The subject device provides visualization of tractography information as an additional modality, whereas, this capability is not provided by the predicate device. Since the latter two technologies are provided as optional features in the respective systems they are not intended to mitigate specific risks. Hence, these disparities do not introduce any new risks.

## VII. PERFORMANCE DATA

The following testing was conducted on BrightMatter Navigation system:

- Tracking accuracy as positional error and angular error using a measurement phantom that mimicked the brain volume. Value of the measurement phantom was obtained using a Coordinate Measurement Machine (CMM) and used as truth data. CT image of the same phantom was used to simulate the clinical workflow during this measurement. The slice thickness of the CT image was 0.625 mm. Positional error was measured to be less than 2 mm and angular error was measured to be less than 2 degrees.
- Software verification and validation testing for each requirement specification.
- System integration testing using anatomical phantoms.
- Safety testing using external test laboratories.

The following quality assurance measures were applied during development of the software component of the system:

- Software Development Life Cycle
- Software Risk Assessment.
- Risk Assessment of Off-the-Shelf (OTS) Software.
- Software Configuration Management and Version Control.
- Software issue tracking and resolution.

*Design Validation*: Design validation was performed using the BrightMatter Navigation System in actual and simulated use settings. The results support substantial equivalence to the predicate device and demonstrate that the BrightMatter Navigation system is safe for its intended use.

*Clinical Testing*: This technology is not new, therefore a clinical study was not considered necessary prior to release.

## VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the hardware verification and validation demonstrate that the BrightMatter Navigation system should perform as intended in the specified use conditions. The non-clinical data demonstrate that the BrightMatter Navigation system device perform comparably to the predicate device that is currently marketed for the same intended use.